

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **MAIL STOP PATENT APPLICATION**  
Yoshiharu HAYASHI et al. :  
Serial No. NEW :  
Filed February 23, 2004 : Attorney Docket No. 2004\_0298

METHOD FOR PROPHYLAXIS AND  
TREATMENT OF DIABETIC  
COMPLICATIONS WITH 4[ $\alpha$ -  
HYDROXY-2-METHYL-5-  
(1-IMIDAZOLYL)BENZYL]-3,5-  
DIMETHYLBENZOIC ACID AND  
DERIVATIVES  
(Rule 1.53(b) Continuation  
of Serial No. 10/354,136,  
Filed January 30, 2003)

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449.

A legible copy of each reference listed on the form PTO-1449 and each U.S. patent application listed below is enclosed, except a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior parent application Serial No. 10/354,136.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

**and thus no certification and/or fee is required.**

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and**

**the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

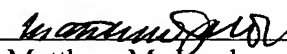
2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
  - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
  - c. ☐ the concise explanation contained in the specification of the present application at page ,
  - d. ☐ the concise explanation set forth in the attached English language abstract,
  - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.

Respectfully submitted,

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February 24, 2004

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)

Date Submitted to PTO: February 24, 2004

ATTY DOCKET NO.  
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NEWAPPLICANT  
Yoshiharu HAYASHI et al.FILING DATE  
February 23, 2004

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,661,603	4/1987	Tsuruda et al.			
	AB	4,448,781	5/1984	Cross et al.			
	AC	4,882,347	11/1989	Cozzi et al.			
	AD	4,737,506	4/1988	Shimizu et al.			
	AE	5,091,191	2/1992	Oda et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AF	63-119425	5/1988	Japan			
	AG	0 379 579	8/1990	Europe			
	AH	0 427 860	5/1991	Europe			
	AI	38 18 741	12/1986	Germany			
	AJ	61-277670	12/1986	Japan			
	AK	2-704	4/1980	Japan			
	AL	3-7281	1/1991	Japan			

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	M. Tsuruda et al., <u>J. Pharm. Soc. Jap.</u> , 109(1), 26-32 (1989).
	AN	W. Erdbrügger et al., <u>Proq. Clin. Biol. Res.</u> , 301, 389-394 (1989).
	AO	Y. Ono et al., <u>Prostaglandins Leukot. Essent. Fatty Acids</u> , 53, 139-145 (August 1995).
	AP	H. Sone et al., <u>Life Sciences</u> , 58(3), 239-243 (1996).

EXAMINER

DATE CONSIDERED

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA	6,060,496	5/2000	Hayashi et al.			
	BB	5,401,851	3/1995	Boyd et al.			
	BC	5,484,780	1/1996	Boyd et al.			
	BD	6,258,834	7/2001	Hayashi et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	BE	P93 01603	6/1993	Hungary			

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	BF	C. Patrono et al., <u>J. Lipid Mediators</u> , <u>6</u> , 411-415 (1993).
	BG	Y. Matsuo et al., <u>Pharmacology</u> , <u>50</u> (1), 1-8 (January 1995).
	BH	K. Hora et al., <u>Nephron</u> , <u>56</u> (3), 297-305 (1990).
	BL	S. Katayama et al., <u>J. Lab. Clin. Med.</u> , <u>109</u> (6), 711-717 (1987).
	BJ	Kudome et al., CA 110:18546, 1989.
	BK	Kyoto Pharmaceutical Industries, Ltd., CA 114:143418, 1991.
	BL	An English translation of Kudome et al. (JP 63-119425), 1998.
	BM	An English translation of Tsuruda et al. (J. Pharm. Soc. Of Japan, Yakugaku Zasshi, January 1989, Vol. 109, No. 1, pages 26-32).
	BN	An English translation of Matsui et al. (JP 03-7281) 1991,

EXAMINER

DATE CONSIDERED